IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. LIQUIDIA TECHNOLOGIES, INC., Defendant.	)	[redacted] C.A. No. 23-975-RGA-SRF **Redacted - Public Version**

DEFENDANT LIQUIDIA TECHNOLOGIES, INC'S RESPONSE REGARDING BOND FIGURES

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During the April 23, 2024 hearing on UTC's preliminary injunction motion, the Court requested the parties submit information regarding the amount of a bond UTC would need to post in the event the Court granted a preliminary injunction, enjoining Liquidia from launching Yutrepia™ in the PH-ILD indication until the conclusion of trial. Liquidia responds as follows.

A. Categories of Costs and Damages That Would Be Suffered by Liquidia

If the Court were to grant UTC's preliminary injunction motion, the Court will have to make findings that UTC will suffer irreparable harm if Liquidia launches in PH-ILD. UTC contends that its harm is irreparable because, *inter alia*, a Yutrepia™ launch in PH-ILD will impact market dynamics for both the PAH and PH-ILD indications that would persist for years. D.I. 26, 16-19. Because Liquidia and UTC are the only two competitors in the relevant market, Liquidia would necessarily suffer comparable irreparable damages if it is enjoined from launching in PH-ILD and the '327 patent is later found to be invalid, unenforceable and/or not infringed. That is, Liquidia would not only suffer harm with respect to the PH-ILD indication, but also with respect to the PAH indication because, as admitted by UTC during the April 23rd hearing, payors would likely not include Yutrepia™ on their formulary plans for PAH, which would not be enjoined. PI Hearing Tr. at 27:22-28:21, 30:10-14.[1]

If the Court preliminarily enjoins Liquidia from launching Yutrepia™ for PH-ILD, Liquidia would not be able to simply launch Yutrepia™ in PAH as UTC suggests. D.I. 26, 19-20. Yutrepia's launch for PAH would be delayed to allow time for amendment and approval of its amended NDA. Liquidia would also suffer additional harm including repackaging and relabeling costs, increased FDA expenditures, and potential ancillary litigation with UTC regarding the

[1] Given the size of the market, which UTC estimated to be [redacted] total patients by [redacted] and [redacted] patients by [redacted] (*see* D.I. 52, Ex. 26 (UTC_PH-ILD_009410) at 009413) this impact on market dynamics would be substantial.

applicability of a 30-month stay to the PH-ILD indication or other issues related to the process by which Liquidia seeks to add PH-ILD to the label for Yutrepia™. More specifically, the following, non-exhaustive regulatory and pre-launch activities would need to occur:

- Liquidia would be required to withdraw its properly filed July 2023 NDA amendment adding the PH-ILD indication to NDA No. 213005.[2]
- Liquidia would need to generate a new Yutrepia™ label removing all information related to PH-ILD.
- The FDA would need to re-review the new Yutrepia™ label and subsequently grant final FDA approval to NDA No. 213005 for the PAH indication.
- Once final NDA approval is granted, Liquidia would need to re-package and re-label its Yutrepia™ product to reflect only the PAH indication, which would take approximately 2-3 months.
- After final FDA approval for Yutrepia™ in PAH, Liquidia would need to submit a supplemental NDA adding the PH-ILD indication and serve a new Paragraph IV certification on UTC regarding the '327 patent and any other previously listed Orange Book listed patents, including the '793 patent if UTC continues to list it despite its invalid status.
- If Liquidia submits a new Paragraph IV certification, UTC would presumably file a new Hatch-Waxman litigation.
- If UTC were to file a new Hatch-Waxman litigation, UTC will likely argue that it is entitled to a 30-month stay of FDA approval on the PH-ILD indication. Although UTC is legally incorrect, it has made an argument to the District Court for the District of Columbia in conjunction with its APA action filed against the FDA that if Liquidia seeks to obtain approval for the PH-ILD indication through a means other than the currently pending NDA, UTC would be entitled to a new 30-month stay. Indeed, the purported loss of a 30-month stay is the "harm" UTC alleged gave rise to its cause of action against the FDA. As a result, Liquidia and the Court will need to address ancillary litigation as to whether UTC is entitled to a 30-month stay of FDA approval.

[2] By withdrawing its amendment adding the PH-ILD indication, the Court would technically lose jurisdiction over the case as there would be no pending NDA submission giving rise to UTC's Hatch-Waxman litigation.

- UTC would likely request a re-setting of the current June 2025 trial date, further delaying resolution and maintaining UTC's preliminary injunction beyond what is currently contemplated by the Court and parties. D.I. 45.

- The FDA would engage in a new FDA review period for the PH-ILD indication (potentially lasting 8 months), despite the fact that the FDA previously began reviewing Liquidia's NDA and PH-ILD indication in 2023.

These events are not speculative in nature but would be a direct result of a PH-ILD preliminary injunction. They would also lead to direct monetary and time losses to Liquidia in the PAH indication. Given UTC's actions to date, including proceedings before this Court and other attempts by UTC in federal district court, state court, and the Federal Circuit to seek additional injunctions and stay of judgments, it is safe to assume UTC will avail itself of all available avenues to delay competition—even lawful competition in PAH.

Finally, there would also be significant harm to Liquidia that is difficult to quantify. For example, Liquidia has engaged a work force that is sized to support a launch of Yutrepia™ into both the PAH and PH-ILD indications. If Liquidia was enjoined from launching for PH-ILD, it would need to re-evaluate the size of its work force given the more limited market for its product. Similarly, due to the reduction in Liquidia's revenues and additional resources (both monetary and otherwise) that would need to be directed towards continued efforts to seek approval of PH-ILD, Liquidia would have less resources available for research and development of its next generation product for the treatment of PAH and PH-ILD.

All of these factors must be considered in assessing the costs and damages suffered by Liquidia if it is later found to have been wrongfully enjoined. Taking into account all of these harms and costs in light of a PH-ILD injunction, the balance of hardships tips heavily in Liquidia's favor. Coupled with the more than substantial question Liquidia raised with respect to the invalidity of the '327 patent and the lack of actual evidence of irreparable harm to UTC, UTC's motion for preliminary injunction should be denied.

B. UTC's Bond

As supported by Liquidia's internal projections (*see* Ex. 1), UTC should post a bond of $300,000,000 if the Court grants a preliminary injunction preventing Liquidia's launch in PH-ILD from now until the June 2025 trial[3]. This bond would partially offset the economic harm resulting from the injunction, including loss of any sales for PH-ILD, delayed launch in PAH as a direct result of the preliminary injunction, a reduction in sales in PAH even after launch and the direct costs associated with re-packaging and labeling. The $300M bond does not, however, account for the changes in market dynamics, discussed above, that Liquidia would suffer if a preliminary injunction in PH-ILD were granted, which would be substantial.

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[3] An accounting of damages post-trial would need to be conducted and take into account any further delay in resolution.

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Dated: April 26, 2024

CERTIFICATE OF SERVICE

I hereby certify that on April 26, 2024, this document was served on mnat_ip_efiling@morrisnichols.com and the persons listed below in the manner indicated:

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EXHIBIT 1

[redacted]

PAH /PH-ILD Launch	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25
Net Revenue - Total	[redacted]																
Net Revenue - PAH	[redacted]																
Net Revenue - PH-ILD	[redacted]																

No PH-ILD Launch	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25
Net Revenue - Total	[redacted]																
Net Revenue - PAH	[redacted]																
Net Revenue - PH-ILD	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -

Lost Net Revenue to Liquidia	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25
Net Revenue - Total	[redacted]																
Net Revenue - PAH	[redacted]																
Net Revenue - PH-ILD	[redacted]																